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**Questions and Answers on**

**Use of Vaccine Purchased with 317 Funds**

**Beginning October, 1, 2012, Section 317 vaccine funds may no longer be used to vaccinate fully insured individuals. (This includes inventory in your clinic prior to Oct. 1st as well)**

The following policy clarifications *only* apply to Section 317 vaccine funding. Vaccines for Children (VFC) will continue to provide vaccines for uninsured children, Medicaid eligible children, and American Indian/Alaska Native children.

1. **Does the CDC have the authority to implement this policy?**

Yes. CDC has the authority as well as the responsibility for the administration of 317 funds under the enacting legislation and 45 CFR 92. Given this responsibility, CDC is implementing this policy in continued efforts to ensure fiscal accountability for these funds.

**2. Why is CDC putting this policy into effect now?**The 317 program has evolved over time to fill gaps and address priorities in our vaccine programs. As Affordable Care Act is implemented, more individuals will have coverage for vaccines through both public and private insurance, and nearly ***all*** children will be covered through VFC or private insurance. While childhood vaccination coverage is at record highs, there are many gaps in uninsured adults. With the changes in insurance coverage it is time to allow 317 to evolve once again to best address the needs of the individuals served by our vaccine programs.

**3. What is CDC definition of under- and fully-insured?**The terms “underinsured” and “fully insured” are defined as follows:

* **Underinsured**: A person who has health insurance, but the coverage does not include vaccines or a person whose insurance covers only selected vaccines. Children who are underinsured for selected vaccines are VFC-eligible for non-covered vaccines only. Underinsured children are eligible to receive VFC vaccine only through a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC) or under an approved deputization agreement.
* **Fully Insured:** Anyone with insurance that covers the cost of vaccine, even if the insurance includes a high deductible or co-pay, or if a claim for the cost of the vaccine and its administration would be denied for payment by the insurance carrier because the plan’s deductible had not been met.

**4. What can 317 vaccines NOT be used for?** The clarification of the 317 vaccine policy, generally, focuses on ensuring that insured individuals receive their vaccinations through their insurance provider network, and are not subsidized through federal funding.   
PA Department of Health may not administer Section 317 vaccines to fully insured children or adults, except in limited circumstances described below. An underinsured child may receive Vaccines for Children (VFC) funded vaccine if the child is seeking vaccinations in a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC) or under approved deputization agreements.   
  
In circumstances other than “exceptions” specified in the policy, 317 vaccines may **not** be used to vaccinate:

* Fully insured children and adults seen in public clinics
* Fully insured children and adults seen in private provider offices
* Adults with Medicare Part B
* Adults with Medicaid coverage for vaccines
* Fully insured adults seen in STD/HIV clinics or drug treatment centers
* Fully insured parents of newborn infants participating in Tdap cocooning projects
* Fully insured adults at high risk for acquiring Hepatitis A
* Fully insured children and adults with a high co-pay or deductible
* Fully insured students receiving vaccines for college entry at Public Health Clinics or College health facilities
* Fully insured children and/ adults in low medical access areas
* Fully insured adults in LTCs/eldercare
* Fully insured children in school-based health centers or clinics
* Fully insured “high risk” occupational groups (e.g. EMS, first responders, health care workers) for hepatitis A or B or other diseases
* Fully insured adults and children receiving vaccines as part of a community wide outreach event (including mobile vans and health fairs)
* Children who are insured by SCHIP standalone programs

**What can 317 vaccines be used for?**Exceptions: 317 vaccine funds may be used to vaccinate the following:

* Newborns receiving the birth dose of hepatitis B prior to hospital discharge that are covered under bundled delivery or global delivery package
* Fully Insured infants of hepatitis B infected women and the household or sexual contacts of hepatitis B infected individuals
* Uninsured or underinsured adults
* Fully insured individuals seeking vaccines during public health response activities including:
  + Outbreak response (regardless of insurance status)
  + Preparedness support
  + Post-exposure prophylaxis
  + Disaster relief efforts
  + Mass vaccination campaigns or exercises for public health preparedness
  + Individuals in correctional facilities and jails

**5. Can we use 317 vaccine for underinsured children?**Underinsured children who are seeking services in an FQHC or under a deputization arrangement are considered VFC eligible and therefore 317 vaccines may not be used. However, if the vaccines are being given at a health care facility that is neither an FQHC nor has it been deputized, then 317 funded vaccines can be used.

* 1. **Definition:** FQHCs and RHCs are permitted to delegate authority to public health department clinics or other providers to address situations in which the FQHC or RHC capacity to vaccinate underinsured children is exceeded by the number of underinsured children. (PA has met with the PA Community Health Centers umbrella organization to discuss and we are working on a Memorandum of Understanding agreeable to both parties. Once approved direction will be forthcoming on how to and who shall request deputization from a local FQHC/RHC) )

**6. Some of our fully insured clients have very high deductibles; can we use 317 vaccine funds to immunize them if they have not met their deductible?**No. Section 317 vaccine may not be used to routinely vaccinate any fully-insured individual. 317 vaccine may be used to vaccinate under-insured individuals whose insurance does not cover vaccination.

It should be noted that research done by the Kaiser Family Foundation indicates that individuals with high deductible health plans (HDHP) are a very small proportion of the insured population. Additionally, the study states that many HDHPs routinely cover preventative services without requiring the deductible is met. The CDC encourages grantees to contact insurers to determine their specific HDHP policies and benefits. The majority of covered workers with a deductible are in plans where the deductible does not have to be met before certain services, such as physician office visits, preventive care, or prescription drugs, are covered. Specifics from the report include:

* Roughly 84% of covered workers with general plan deductibles in HMOs, POS plans (68%), and PPOs (74%) are enrolled in plans where the deductible does not have to be met before physician office visits for primary care are covered
* Higher shares of covered workers do not have to meet the deductible before preventive care is covered in HMOs (96%), PPOs (93%), POS plans (88%), and HDHP/SOs (94%)

The full report can be found at: <http://ehbs.kff.org/pdf/2011/8225.pdf>

**7. Can 317 vaccine funds be used for birth doses of Hepatitis B.**

Yes. VFC and Section 317 may be used for the birth dose of hepatitis B. The CDC wants to ensure that important strides made in vaccination coverage are not compromised.

**8. Can we continue funding Tdap cocooning programs with 317 vaccine? (Tot Trax )**No.Tdap cocooning programs may not be funded with 317 vaccines.

**9.** **If a clinic starts an insured client now on a series vaccine can we finish them or do we have to turn them away for the follow ups?**

As of October 1, 317 funded vaccine may not be used to complete a vaccine series for insured so should be referred to provider.

**10. Can we continue using 317 vaccines for our school-located influenza vaccine clinics?**Yes, for the 2012-2013 influenza season, we have indicated that 317 vaccine funds may be used to support mass vaccination clinics, and 317 vaccine can be used to respond to disease outbreaks. It is important to clarify however, that we do not expect 317 vaccine funds will be used routinely for other school-based vaccination efforts.

**11. Can we use our influenza vaccine purchased with 2012 317 funds to vaccinate fully insured individuals in upcoming influenza outreach clinics, even if they fall after the October 1 deadline?**Yes, Grantees are encouraged to use their FY 2012 Section 317 influenza vaccine for fall influenza outreach clinics even if they fall after the October 1 deadline.

**12. Can we use 317 vaccine for non-Medicaid covered vaccines?**Yes, if Medicaid does not cover a vaccine for adults, the adult is considered underinsured for that vaccine and may receive 317 funded vaccines.

**13**. **Can we use 317 vaccine for immigrants and refugees?**Yes, since PA does not provide immigrants and refugees with medical benefits and the individuals do not have employer sponsored health insurance, then they are considered uninsured and may be vaccinated with 317 funded vaccines. (Note: We are not authorized to verify citizenship).

**14. What is the role of the Section 317 Immunization Program?**

The Section 317 Immunization Program plays a critical role in achieving national immunization coverage targets and reductions in disease. Behind every vaccine given to a child, adolescent, or adult in the United States are public health systems and experts that are essential to a successful immunization program that will continue to be critical following the implementation of the health insurance reforms of the Affordable Care Act.

**15. What will its role be after Affordable Care Act implementation?**While the Affordable Care Act expands insurance coverage for immunization services, other important public health functions are necessary to assure that the right vaccines get to the right people at the right time to protect their health and the health of their communities and prevent resurgences of life-threatening diseases. The Section 317 Immunization Program is needed to support those functions.

**16. With Affordable Care Act upheld, is this policy still moving forward?**Yes. This policy goes into effect beginning October 1, 2012. The 317 vaccine funding policy is not dependent on Affordable Care Act (ACA), although improvements in vaccine coverage mandated by the ACA will facilitate implementation. This policy is to ensure that we are all doing our part to ensure responsible fiscal management of public resources.

**17. Does this policy change mean that CDC is changing the Section 317 program to only serve adults?**

No - It will no longer be appropriate for Section 317 vaccine to be used for routine vaccination of children, adolescents, and adults who have public or private insurance that covers vaccination.

**18. Does CDC have any information on when “grandfathered” insurance plans will lose their “grandfather” status and how many of these plans still exist?**

**Definition: Grandfathered Health Plan:** As used in connection with the Affordable Care Act; A group health plan that was created or an individual health insurance policy that was purchased on or before March 23, 2010. Grandfathered plans are exempted from many changes required under the Affordable Care Act. Plans or policies may lose their “grandfathered” status if they make certain significant changes that reduce benefits or increase costs to consumers. A health plan must disclose in its plan materials whether it considers itself to be a grandfathered plan and must also advise consumers how to contact the United States Department of Labor or the United States Department of Health and Human Services with questions. (Note: If you are in a group health plan, the date you joined may not reflect the date the plan was created. New employees and new family members may be added to grandfathered group plans after March 23, 2010).

According to a presentation given by the AMA at the Adult Immunization Summit earlier this year, approximately 50% of plans had grandfathered status in 2011 with half of those expected to lose that status in 2012. Small plans are likely to lose grandfathered status quicker than large plans and it is estimated that 90% of grandfathered plans will lose their grandfathered status by 2014.

The CDC recommends clear and consistent communication regarding the Section 317 vaccine policy to affected individuals in order to provide these individuals the time necessary to understand their specific insurance policy and plan for the future.

**19. Can American Indian and Alaska Native Adults be vaccinated with 317 vaccine?**American Indian and Alaska Native adults whose only source of health care is provided by an Indian Health Service, Tribal or Urban health care organization that does not provide an ACIP-recommended vaccine can receive 317 funded vaccine if the vaccine is otherwise not available because they are not insured. In addition, it is CDC’s understanding that the IHS Chief Medical Officer plans to send out a memo stating that IHS considers provision of all ACIP recommended vaccines to be a basic standard of care, and strongly encourage all sites to provide all routinely recommended vaccines.

**20. Zoster vaccine is not covered by Medicare Part B.  May I vaccinate adults on Medicare Part B with 317 funded Zoster?  What if Zoster vaccine is not covered by Medicare Part D?**Medicare Part B does not cover certain vaccines, including Zoster, Tdap or Td.  However, all Medicare Part D plans are required to cover ACIP-recommended vaccines not covered under Medicare Part B.  Thus if the individual has both Medicare Part B and Part D, he/she is considered fully insured for vaccines and may not receive 317 funded vaccines.  If the individual does not have Medicare Part D coverage, then he/she is considered underinsured for those vaccines and may receive 317 funded vaccines.   

**21.** T**here has been a change in medical assistance where a patient is only covered for a maximum of 6 prescriptions per month.**   This includes any injections including flu. The advice they received is that they can request an exception and medical assistance may cover these injections.  However, there is no guarantee that the doctor will be reimbursed.   So the doctor does not want to proceed with these immunizations.   The issue is not only reimbursement, but also the amount of paperwork and time to process the request.   **At this point, the doctor’s office wants to know if these clients should be referred to the SHC to receive their flu shots and PNU shots when they exceed their public assistance limit?**

**No –** the physician should try and work it out for the patient to receive vaccines and prescriptions in a month without exceeding the six prescription limit. This is a link highlighting this issue. <http://www.phlp.org/wp-content/uploads/2012/01/Rx-reduction-fact-sheet-2012.pdf>